

**Remarks**

Claims 40 and 62-65 were pending. By this amendment, claim 40 and 65 are amended. Support for these claim amendments can be found throughout the specification, including page 40, line 2 – 16. Claim 63 is canceled without prejudice. Applicants reserve the right to pursue canceled subject matter in continuing applications.

No new matter is introduced by the foregoing amendments. Entry of the amendment after final is proper because it places the claims in condition for allowance. After entry of this amendment, claims 40, 62, 64 and 65 are pending in the application. Reconsideration of the pending claims is respectfully requested.

***Examiner Interview***

Applicants thank Examiner Swope for having a telephone interview with the undersigned on October 22, 2010. During the interview, the rejections under 35 U.S.C. §§ 101, 112 and 102 were discussed. In particular, the amendment of claim 40 to clarify the specific steps in the process claim were discussed. Also discussed was the finality of the Office action. Examiner Swope agreed to consider the amended claim and to call the undersigned to discuss any further amendments that might place the claims in condition for allowance. Examiner Swope also agreed to discuss the finality of the Office action with her supervisor and to consider our arguments as to why the finality was improper. Applicants believe that this response is prepared in accordance with the suggestions provided by Examiner Swope.

***Improper Issuance of Final Office action***

Applicants request that the finality of the office action be withdrawn because it is improper for at least the following reasons. First, the Office cites MPEP §706.07(a) for supporting the finality of the Office action (See, Page 10, lines 1-5 of the Office action). Applicants assert that MPEP §706.07(a) is not applicable because it relates to when a final office action is proper on a second action. Here, the final office action was issued immediately after an RCE was filed. An RCE is considered to be a first action. Therefore, MPEP §706.07(a) cannot and does not apply. Instead, whether a final office action is proper after an RCE is filed is

governed by MPEP §706.07(b). Therefore, the issuance of a final office based upon MPEP §706.07(a) is improper on this basis alone.

Even if the proper MPEP section, §706.07(b), were to have been applied, the issuance of a final office action is still improper. As stated in MPEP §706.07(b): “claims of an application for which a request for continued examination (RCE) has been filed may be finally rejected in the action immediately subsequent to the filing of the RCE (with a submission and fee under 37 CFR 1.114) where all the claims in the application after the entry of the submission under 37 CFR 1.114 (A) are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114, and (B) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to the filing of the RCE under 37 CFR 1.114.” Here, claims 64 and 65 were newly added and were not drawn to the same invention claimed in the application prior to the entry of the submission. Further, the claim amendments necessitated new grounds of rejection (both 35 U.S.C. §§ 101 and 102(b) rejections) and the citation of art that was not previously relied upon by the Office (Pannecouque *et al.*, *Current Biol.* 12: 1169-1177, 2002 and Lin *et al.*, *Proc. Natl. Acad. Sci.* 100(19): 11013-11018, 2003). Therefore, the standards set forth by 37 CFR 1.114(A) and (B) have failed to be satisfied. As such, Applicants believe that the issuance of a final Office action was improper and request that the finality of such be withdrawn.

### ***Claim Objections***

Claims 40, 62 and 63 are provisionally objected to for encompassing non-elected subject matter. Claim 40 has been amended to be directed to a method for identifying an agent that decrease HIV-1 infection. Further, claim 62 depends from claim 40 and claim 63 has been canceled. As stated in the Office action (page 2), “the currently examined invention is directed to a cellular method for identifying an agent that decrease HIV-1 infection.” Applicants believe that these amendments render the pending objections moot and request that they be withdrawn.

### ***Claim Rejections***

#### **35 U.S.C. § 112, second paragraph**

Claims 40, 62 and 63 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. In particular, claim 40 is alleged to be indefinite for reciting the term “associating.” Although Applicants disagree with the Examiner and believe that one of skill in the art would know the metes and bounds of the recited invention, in order to further prosecution claim 40 has been amended. In particular, the term “associating” has been removed from claim 40. Applicants believe that the pending claims are definite and request that the pending 35 U.S.C. §112, second paragraph, rejection be withdrawn.

#### **35 U.S.C. § 101**

Claims 40, 62 and 63 have been rejected under 35 U.S.C. §101 as allegedly indefinite. Applicants traverse this rejection for at least the following reasons. Claim 40 includes the three following activity steps: (1) administering a test agent to a cell containing Rab11A; (2) contacting the cell with HIV-1; and (3) detecting a level of HIV-1 infection by assessing Rab11A gene expression or Rab11A activity, wherein a decrease in a decrease of Rab11A gene expression, Rab11A activity, or a combination thereof indicates that the test agent is an agent that decreases HIV-1 infection. As claim 40 clearly sets forth multiple steps involved in the claimed process, claim 40 and all claims that depend therefrom are proper process claims under 35 U.S.C. §101. Applicants request that this pending rejection be withdrawn.

#### **35 U.S.C. § 112, first paragraph**

##### **(a) Enablement:**

Claims 40, 62 and 63 have been rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled by the specification. In particular, the Office contends that the specification does not reasonably provide enablement for any biochemical, cellular or *in vivo* method for identifying an agent that decrease infection of any cell by any virus or retrovirus. Amended claim 40 is directed to a method of identifying an agent that decreases HIV-1 infection. Applicants believe that claim 40 has been amended so that the step of assessing Rab11A gene expression and activity will be given weight as a claim limitation thereby rendering the pending 35 U.S.C. §112, first paragraph, rejection moot. Further, Applicants

respectfully, but adamantly disagree with the pending enablement rejection as it may be applied to the amended claims for at least the following reasons.

As the Office is aware, “[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue” (citing *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976)). Here, although routine assays may be required in order to select optimal screening conditions of the claimed invention, no undue experimentation is required to practice the full scope of the invention. Applicants submit that the emphasis in this test is on “undue,” and not on “experimentation” (see *In re Wands*, 858 F.2d 731, 736-40 (Fed. Cir. 1988)). As the Office is no doubt aware, the determination of what is meant by “undue experimentation” has been characterized by the Federal Circuit as follows (*Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d at 1365):

[t]he test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

In the current case, any necessary experiment is merely routine, and thus not undue. The specification provides numerous exemplary methods for identifying agents that decrease HIV-1 infection by monitoring Rab11A activity or expression, including page 39, line 16 – page 41, line 28, Example 13 and Example 14. All of these methods are routine and known to those of ordinary skill in the art. Therefore, it is believed that any experiment is well within the limits set by the *Genentech* court. The present claims are not so broad to encompass any biochemical, cellular or *in vivo* method. In contrast, the present claims are directed to a specific method that for identifying an agent that decreases a specific virus (HIV-1), by detecting a specific activity (assessing gene expression or activity), of a specific molecule (Rab 11A). As such, Applicants believe that the claims as presented herein are fully enabled by the specification and satisfy the enablement requirement of 35 U.S.C. §112, first paragraph.

**(b) Written Description**

Claims 40, 62 and 63 have been rejected under 35 U.S.C. §112, first paragraph as allegedly failing to satisfy the written description requirement. In particular, the Office contends that the specification does not reasonably provide written description for identifying agents that decrease pathogenicity of all retroviruses by measuring Rab11A activity. Amended claim 40 is directed to a method of identifying an agent that decreases HIV-1 infection. Applicants believe the claims as amended render the pending 35 U.S.C. §112, first paragraph, written description rejection moot. Moreover, as stated above, the specification provides written support for numerous exemplary methods for identifying agents that decrease viral infection by monitoring Rab11A activity or expression, including page 39, line 16 – page 41, line 28, Example 13 and Example 14. Therefore, one of ordinary skill in the art would understand how to perform the claimed method (*i.e.*, identify agents that decrease HIV-1 infection by detecting the level of HIV-1 infection by assessing the level of Rab11A gene expression or Rab11A activity, wherein a decrease in Rab11A gene expression and/or Rab11A activity indicates that the test agent is an agent that decreases HIV-1 infection) and would recognize that Applicants were in possession of the claimed invention at the time of filing. Therefore, the pending claims are sufficiently described by the specification. Applicants believe that the amended claims comply with the written description requirement.

For all of these reasons, Applicants request that the pending 35 U.S.C. §112, first paragraph, rejections be withdrawn.

35 U.S.C. § 102(b)

Claims 40, 62 and 63 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Pannecouque *et al.* (*Current Biol.* 12: 1169-1177, 2002; hereinafter referred to as Pannecouque *et al.*) or Lin *et al.* (*Proc. Nat. Aca. Sci.* 100(19): 11013-11018, 2003; hereinafter referred to as Lin *et al.*). Applicants traverse this rejection for at least the following reasons.

As stated above, independent claim 40 has been amended to include “detecting a level of HIV-1 infection by assessing Rab11A gene expression or Rab11A activity, wherein a decrease in Rab11A gene expression, Rab11A activity, or a combination thereof indicates that the test agent

is an agent that decreases HIV-1 infection.” Thus, all pending claims are directed to a method that involves detecting Rab11A gene expression or activity to identify an HIV-1 infection inhibitor.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Here, anticipation has not been established because neither Pannecouque *et al.* nor Lin *et al.* teach or suggest methods of identifying of identifying an agent that HIV-1 infection by detecting a level of HIV-1 infection by assessing Rab11A gene expression or Rab11A activity as required in independent claim 40. As the cited references do not properly anticipate independent claim 40, such references cannot anticipate any dependent claim therefrom. Therefore, Applicants respectfully request that the presently pending 35 U.S.C. §102(b) rejection be withdrawn.

### Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. The Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution.

Respectfully submitted,

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